

FILED

JAN 16 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CLERK U.S. DISTRICT COURT
WEST. DIST. OF PENNSYLVANIA

UNITED STATES OF AMERICA

v.

THOMAS WHITTEN

20-18
Criminal No.

(18 U.S.C. §§ 2, 371, and 1347; and 21
U.S.C. § 846)

[UNDER SEAL]

INDICTMENT

COUNT ONE

The grand jury charges:

At all times material to this Indictment:

1. THOMAS WHITTEN, M.D. ("WHITTEN") was a Pennsylvania-licensed physician (PA Medical License Number MD038465E).

2. Beginning in and around 2006, THOMAS WHITTEN has maintained a medical practice, called Westmoreland Pain Management Center, located at 4893 Route 30 East, Suite 8, Greensburg, PA 15601.

3. THOMAS WHITTEN applied for and maintained status as a Medicare and Medicaid provider. In and around November and December 2005, THOMAS WHITTEN certified to Medicare that he would comply with all Medicare rules and regulations, including that he would not present or cause to be presented a false or fraudulent claim for payment by Medicare and that he would refrain from violating the federal anti-kickback statute.

4. On or about June 10, 1990, THOMAS WHITTEN certified to Medicaid that he would comply with all applicable federal and Pennsylvania statutes and regulations.

5. Insys Therapeutics, Inc. ("Insys") was a pharmaceutical company incorporated in Delaware and headquartered in Chandler, Arizona.

6. In and around January 2012, the U.S. Food and Drug Administration (“FDA”) approved Insys’s application to sell and market fentanyl under the brand name Subsys (hereinafter, “Subsys”) to patients suffering from breakthrough cancer pain.

7. Subsys was a potent opioid designed to rapidly enter a patient’s bloodstream upon being sprayed under the tongue.

8. Subsys was in a category of drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”). Because of the risk of misuse, abuse, addiction, and overdose associated with TIRF drugs, including Subsys, only practitioners enrolled in the FDA-mandated TIRF Risk Evaluation and Mitigation Strategy program (the “TIRF REMS Program”) were allowed to prescribe TIRF drugs.

9. THOMAS WHITTEN applied for and maintained enrollment as a TIRF REMS provider. On or about October 8, 2013, September 23, 2015, and August 23, 2017, THOMAS WHITTEN re-enrolled as a TIRF REMS provider and completed an attestation to the FDA that he would assess patients to whom he prescribed TIRF drugs, including Subsys, “for appropriateness of the dose” of the TIRF drug, and “for signs of misuse and abuse” at “all follow-up visits.” THOMAS WHITTEN also attested that he understood that TIRF drugs, including Subsys, were “indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain”.

THE CONSPIRACY

10. From in and around May 2013 and continuing thereafter to on or about November 20, 2015, in the Western District of Pennsylvania, the defendant, THOMAS WHITTEN, knowingly and willfully did conspire, combine, confederate, and agree with persons known to the

grand jury, to commit offenses against the United States, that is: Receiving Health Care Kickback, in violation of Title 42, United States Code Section 1320a-7b(b).

MANNER AND MEANS OF THE CONSPIRACY

11. It was a part of the conspiracy that THOMAS WHITTEN would receive remuneration from Insys in the guise of payments for educating medical providers about the drug Subsys, when in fact, and as THOMAS WHITTEN well knew, said remuneration was made in return for WHITTEN prescribing Subsys to his patients and increasing the dosage of Subsys prescriptions for his patients.

12. It was further a part of the conspiracy that THOMAS WHITTEN would receive remuneration in kind from Insys in the form of the employment of "A.W." by Insys and said remuneration was made in return for WHITTEN prescribing Subsys to his patients and increasing the dosage of Subsys prescriptions for his patients.

13. It was further a part of the conspiracy that some of said Subsys prescriptions would be submitted for payment, in whole and in part, by a Federal health care program, namely, Medicare and Medicaid.

OVERT ACTS

14. In furtherance of the conspiracy, and to effect the object of the conspiracy, the defendant, THOMAS WHITTEN, and other persons known to the grand jury, did commit and cause to be committed, the following overt acts, among others, in the Western District of Pennsylvania and elsewhere:

a. In and around May 2013, THOMAS WHITTEN met with Insys representative "K.O."

b. In and around late May 2013, THOMAS WHITTEN began prescribing Subsys to his patients.

c. In and around June 2013 through in and around September 2015, THOMAS WHITTEN regularly met with representatives at Insys, purportedly to educate others about Subsys.

d. In and around June 2013 through on or about November 20, 2015, Insys made payments to THOMAS WHITTEN by check.

e. On or about November 12, 2013, THOMAS WHITTEN met with several Insys executives and sales representatives and discussed among other things WHITTEN's prescribing of Subsys, future payments from Insys to WHITTEN, and future employment of "A.W." by Insys.

f. On or about February 11, 2014, THOMAS WHITTEN and an Insys representative known to the grand jury communicated about future employment of "A.W." by Insys and about WHITTEN's prescribing of Subsys.

In violation of Title 18, United States Code, Section 371.

COUNT TWO

The grand jury further charges:

At all times material to this Indictment:

1. Medicare was a federal health insurance program administered by the Centers for Medicare and Medicaid Services (“CMS”), an agency of the U.S. Department of Health and Human Services. Medicare paid for the reasonable and necessary medical services for people aged 65 and older and some persons under 65 with certain illness and/or disabilities. Medicare was a “health care benefit program,” as defined by Title 18, United States Code, Section 24(b). THOMAS WHITTEN was an authorized Medicare provider until he deactivated his enrollment in 2018 and was bound by the laws, rules, and regulations that govern the Medicare program.

2. Medicaid was a system of medical assistance for indigent individuals who are aged, blind, disabled, or members of families with dependent children. The program was funded by both the federal and state governments. Pennsylvania Medicaid, also known as Medical Assistance, was governed by the Commonwealth of Pennsylvania Department of Public Welfare. Medicaid is a “health care benefit program,” as defined by Title 18, United States Code, Section 24(b). THOMAS WHITTEN was an authorized Medicaid provider and was bound by the laws, rules, and regulations that govern the Medicaid program.

3. Highmark Blue Cross Blue Shield (hereinafter Highmark) was a duly licensed health insurance company doing business in the Commonwealth of Pennsylvania. Highmark was a “health care benefit program,” as defined by Title 18, United States Code, Section 24(b). THOMAS WHITTEN was an authorized Highmark provider until he terminated his enrollment in 2017 and was bound by the laws, rules, and regulations that govern Highmark providers.

4. Medicare, Medicaid, and Highmark paid for covered prescriptions to insured

individuals so long as coverage requirements were met. Prescriptions were required to be reasonable and medically necessary for the diagnosis or treatment of an illness or injury and are required to meet all other applicable statutory and regulatory requirements.

5. Persons known to the grand jury were patients of the defendant, THOMAS WHITTEN, and were insured individuals of Medicare, Medicaid, and Highmark. Medicare, Medicaid, and Highmark, paid prescription drug benefits for said persons known to the grand jury.

THE SCHEME AND ARTIFICE

6. It was part of the scheme and artifice that the defendant, THOMAS WHITTEN, provided prescriptions for controlled substances to persons known to the grand jury, knowing that said prescriptions were issued outside the usual course of professional practice and not for a legitimate medical purpose and knowing that billings would be submitted to Medicare, Medicaid, and Highmark to pay for said unlawful prescriptions. The defendant, THOMAS WHITTEN, thereby caused billings to be submitted to Medicare, Medicaid, and Highmark to pay for said unlawful prescriptions.

7. It was further part of the scheme and artifice that the defendant, THOMAS WHITTEN, knowingly caused Prior Authorization requests to be submitted to said health care benefit programs to ensure payment of said unlawful prescriptions. The defendant, THOMAS WHITTEN, thereby caused billings to be submitted to said health care benefit programs, and their managed care organizations, to pay for said unlawful prescriptions.

EXECUTION

8. From in and around May 2013 and continuing thereafter to in and around March 2017, in the Western District of Pennsylvania, the defendant, THOMAS WHITTEN, did knowingly and willfully execute and attempt to execute the above-described scheme and artifice

to defraud a health care benefit program in connection with the delivery of and payment for health care benefits, items, and services.

All in violation of Title 18, United States Code, Sections 1347 and 2.

COUNT THREE

The grand jury further charges:

From in and around May 2013 and continuing thereafter to on or about November 20, 2015, in the Western District of Pennsylvania and elsewhere, the defendant, THOMAS WHITTEN, did knowingly, intentionally, and unlawfully conspire with persons known to the grand jury, to distribute 40 grams or more of a mixture and substance containing a detectable amount of fentanyl, a Schedule II controlled substance, in the form known as Subsys, contrary to the provisions of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(B)(vi).

In violation of Title 21, United States Code, Section 846.

COUNT FOUR

The grand jury further charges:

From in and around November 2017, and continuing thereafter to on or about December 12, 2019, in the Western District of Pennsylvania and elsewhere, the defendant, THOMAS WHITTEN, did knowingly, intentionally, and unlawfully conspire with persons known to the grand jury, to distribute and dispense Phentermine Hydrochloride and Diethylpropion, each a Schedule IV controlled substance, contrary to the provisions of Title 21, United States Code, Sections 841(a)(1) and 841(b)(2).

In violation of Title 21, United States Code, Section 846.

FORFEITURE ALLEGATIONS

The grand jury re-alleges and incorporates by reference the allegations contained in Counts Three and Four of this Indictment for the purpose of alleging criminal forfeiture pursuant to Title 21, United States Code, Sections 853(a)(2) and 853(p), and Title 28, United States Code, Section 2461(c). Pursuant to Title 21, United States Code, Section 853, upon conviction of an offense in violation of Title 21, United States Code, Section 846, the defendant THOMAS WHITTEN shall forfeit to the United States of America any property used, or intended to be used, in any manner and part, to commit, and to facilitate the commission of, such violations. The property to be forfeited includes, but is not limited to, the following:

- a. Drug Enforcement Administration number BW1239020;
- b. Pennsylvania state license to practice medicine number MD038465E.

A True Bill,


Foreperson


SCOTT W. BRADY
United States Attorney
PA Bar No. 88352